



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/826,519	04/03/2001	Michael A. Innis	1565.006	2840

7590 03/12/2002

David P. Lentini
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,519

Applicant(s)

INNIS ET AL.

Examiner

Janet Epps

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8 is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 USC 119(e) and 35 U.S.C. 120 as follows:

Applicant's Oath/Declaration states that the instant application claims benefit of 60/151,246 and claims priority under 35 USC 120 to application 09/648, 254. See MPEP § 201 which states that for an application which is claiming the benefit under 35 U.S.C. 120 of a prior application, which in turn claims the benefit of a provisional application under 35 U.S.C. 119(e), a suitable reference on the first line of the specification would read, "This application is a continuation of U.S. Application No. 08/---, filed ---, now abandoned, which claims the benefit of U.S. Provisional Application No. 60/---, filed ---."

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lamond et al., Kandimalla et al., and Baracchini et al., and further in view of Rösch et al.

Applicant's arguments filed 12-31-2001 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that the prior art does not show or suggest compounds having a central phosphorothioate-linked region flanked by regions of seven to twelve phosphodiester linkages. Furthermore, Applicants argue that the results observed in the antisense assays using antisense oligonucleotides 13038 and 13040, as described in Baracchini et al., "would not motivate one skilled in the art to employ such compounds having any phosphodiester-linked flanked regions, much less longer flanking regions (eg. seven to

Art Unit: 1635

twelve phosphodiester-linked ribonucleotides), as presently claimed.” First, it is noted that Applicants are improperly relying upon the cellular behavior of antisense oligonucleotides having a specific modification and targeted to a specific mRNA sequence, to define how one of ordinary skill in the art would have expected other antisense oligonucleotides of different sequence having the same or similar modifications to behave within a cell in general. It is well known in the art that the efficacy of an antisense oligonucleotide is dependent upon the structure of its mRNA target, and the accessibility of its target sequence. Furthermore, contrary to Applicant’s arguments, one of skill in the art would not accept on its face that the behavior of the modified antisense oligonucleotides of Barachini et al. would necessarily predict the efficacy of all antisense oligonucleotides having the same or similar structure and modifications as those disclosed in Barachini et al. Furthermore, Applicant’s specification does not provide any evidence of unexpected results indicating that their chimeric oligonucleotides according to the formula recited in the instant claims would necessarily possess enhanced “antisense” properties over that described for the antisense oligonucleotides of Barachini et al. in the same cellular environment. As stated in the prior Office action (bridging paragraph of pages 7-8), the ribonucleotide range of seven to twelve in X1 and X2 and the deoxyribonucleotide range of five to twelve in Y does not appear to impart any benefit or advantage other than the expected properties taught in the prior art, namely that such modifications are often preferred over native forms because of desirable properties such as, for example, enhanced cellular uptake, enhanced affinity for nucleic acid target and increased stability in the presence of nucleases (see Barachini et al. col. 6).

Art Unit: 1635

Conclusion

3. Claim 8 is free of the prior art. The prior art does not teach or suggest the chimeric oligonucleotide recited in claim 8. Although the prior art generically discloses the benefits of synthesizing oligonucleotides comprising the modifications according to the present invention, the prior art does not teach oligonucleotides comprising the sequence according to SEQ ID NO: 9 and 10 and further comprising said modifications.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1635

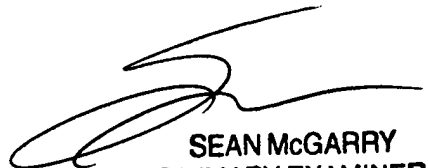
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on M-T, Thurs-Friday 8:30AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635

JLE
March 6, 2002



SEAN MCGARRY
PRIMARY EXAMINER